SECTION 2. SUMMARY AND CERTIFICATION

2.A. 510(K) SUMMARY

Submitter: SterilMed, Inc.

Contact Person:
Dr. Bruce R. Lester
SterilMed, Inc.
11400 73rd Avenue North
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Date Prepared: December 17, 2004

Trade Name: SterilMed Reprocessed Deflectable Electrophysiology Diagnostic Catheter

Classification Name: and Number: Electrode Recording Catheter
Class II, 21 CFR 870.1220

Product Code: NLH

Predicate Device(s): The SterilMed reprocessed deflectable electrophysiology diagnostic catheter is substantially equivalent to: the A20 (K953768), manufactured by Biosense Webster (formerly known as Cordis Webster); the Bard Dynamic Tip Catheter (K912213), manufactured by C.R. Bard Inc.; and their counterparts from the original manufacturers.

Device Description: The device consists of a reprocessed catheter that has a high-torque shaft with a handle at the proximal end, and is steerable. These catheters have an outer diameter of 5F to 7F, a length ranging from 80 to 115 cm, with 4-10 platinum, radiopaque electrodes along the tip shaft and a variety of inter-electrode spacings and curve styles at the tip. The tip is deflectable. Specific cables, as recommended by the original manufacturer, connect to the handle and interface between the catheter and an external stimulator and/or an electrophysiologic recorder. It should be noted that this submission pertains to the catheter only. It does not include any other components in a system such as connector cables, external stimulators, or electrophysiologic recorders.

Intended Use:

The SterilMed Reprocessed Electrophysiology Diagnostic Catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and stimulation. They also provide temporary pacing for the evaluation of cardiac arrhythmias, and are used for electrophysiology mapping of cardiac structures during these evaluations.

Functional and Safety Testing:

Representative samples of reprocessed deflectable electrophysiology diagnostic catheters underwent design testing to demonstrate appropriate functional characteristics, and biocompatibility testing to demonstrate compatibility of the device materials. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The deflectable electrophysiology diagnostic catheters reprocessed by SterilMed are substantially equivalent to the A20 (K953768) manufactured by Biosense Webster (formerly known as Cordis Webster) and the Bard Dynamic Tip Catheter (K912213) manufactured by C.R. Bard Inc., and their counterparts from the original manufacturers. This conclusion is based upon the fact that these devices are identical to the predicate devices in terms of their design, materials, indications for use, and construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2005

SterilMed, Inc.
Bruce Lester, Ph.D.
Vice President Research and Development
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K043513
Trade Name: Sterilmed Reprocessed Deflectable Electrophysiology Diagnostic Catheters
(See Enclosed List)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: NLH
Dated: December 17, 2004
Received: December 20, 2004

Dear Dr. Lester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Model numbers

No.	BiosenseWebster (47 Models)	Bard (18 Models)
1	D5-08D-P10-FS	200131
2	D5-08D-P10-RT	200344
3	D5-DL-005-PS	200345
4	D5S-06AL-252-FS	200443
5	D5S-270L-B02-PS	201101
6	D5S-AL-252-PS	201102
7	D6-06DR-002-FS	201103
8	D6-08DR-002-FS	201104
9	D6-08DR-002-RT	201105
10	D6-08DR-252-RT	201106
11	D6-10DR-282-RT	201107
12	D6-10DR-P10-FS	201108
13	D6-10DR-P10-RS	201109
14	D6-10DR-P10-RT	201110
15	D6-DR-005-PS	201112
16	D6-DR-010-PS	201113
17	D6-DR-231-PS	201114
18	D6-DR-252-PS	201115
19	D6-QA-005-PS	-
20	D6-QD-010-PS	-
21	D6-QF-005-PS	-
22	D6S-08DR-PRY-FS	-
23	D6S-270L-252-PS	-
24	D7-06DL-002-FS	-
25	D7-08DL-002-FS	-
26	D7-08DR-002-FS	-
27	D7-08DR-002-RT	-
28	D7-08DR-005-FS	-
29	D7-08DR-252-RT	-
30	D7-08R-HIS-FS	-
31	D7-08R-HIS-RT	-
32	D7-10DR-282-RT	-
33	D7-10DR-P10-FS	-
34	D7-10DR-P10-RS	-
35	D7-10DR-P10-RT	-
36	D7-10FR-252-RT	-
37	D7-270RG-252-PS	-
38	D7-270RL-252-PS	-
39	D7-DL-005-PS	-

40	D7-DL-010-PS	-
41	D7-DL-252-RT	-
42	D7-DR-005-PS	-
43	D7-DR-010-PS	-
44	D7-DR-252-PS	-
45	D7-PSL-252-PS	-
46	OD7-3X4D-010-FS	-
47	OD7-8X2D-005-FS	-

Indications for Use

510(k) Number (if known): K043513

Device Name: Reprocessed Deflectable Electrophysiology Diagnostic Catheters

Indications For Use:

The SterilMed Reprocessed Electrophysiological Diagnostic Catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and stimulation. They also provide temporary pacing for the evaluation of cardiac arrhythmias, and are used for electrophysiology mapping of cardiac structures during these evaluations.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043513